

107TH CONGRESS  
2D SESSION

# H. R. 5478

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2002

Mr. BILIRAKIS (for himself, Mr. BROWN of Ohio, Mr. TAUZIN, Mr. DINGELL, Mr. UPTON, Mr. WAXMAN, Mr. GREENWOOD, Mr. BOUCHER, Mr. BURR of North Carolina, Mr. TOWNS, Mr. WHITFIELD, Mr. PALLONE, Mr. GANSKE, Mr. DEUTSCH, Mr. NORWOOD, Mr. RUSH, Mr. TERRY, Mr. ENGEL, Mr. SAWYER, Mr. WYNN, Mr. GREEN of Texas, Ms. MCCARTHY of Missouri, Ms. DEGETTE, Mr. BARRETT of Wisconsin, Mr. DOYLE, Mr. JOHN, and Ms. HARMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Patient Safety and  
5       Quality Improvement Act”.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—The Congress finds as follows:

3 (1) In 1999, the Institute of Medicine released  
4 a report entitled “To Err Is Human” that described  
5 medical errors as the 8th leading cause of death in  
6 the United States, with as many as 98,000 people  
7 dying as a result of medical errors each year.

8 (2) To address these deaths and injuries due to  
9 medical errors, the health care system must identify  
10 and learn from such errors so that systems of care  
11 can be improved.

12 (3) Myriad public and private patient safety ini-  
13 tiatives have begun. The Quality Interagency Coordi-  
14 nation Task Force has recommended steps to im-  
15 prove patient safety that may be taken by each Fed-  
16 eral agency involved in health care and activities re-  
17 lating to these steps are ongoing.

18 (4) The Department of Health and Human  
19 Services has initiated several patient safety projects.  
20 The Joint Commission on Accreditation of  
21 Healthcare Organizations issued a patient safety  
22 standard that went into effect on July 1, 2001, and  
23 the peer review organizations are conducting ongoing  
24 studies of clinical performance measurement of care  
25 delivered to beneficiaries under the medicare pro-  
26 gram under title XVIII of the Social Security Act.

1           (5) Several steps can be taken now to improve  
2       patient safety. For example, according to the Cen-  
3       ters for Disease Control and Prevention, hand wash-  
4       ing is the single most important means of preventing  
5       the spread of infection. Repeated studies indicate  
6       that lack of or improper hand washing still contrib-  
7       utes significantly to disease transmission in health  
8       care settings. Working with experts from the private  
9       sector, the Centers for Disease Control and Preven-  
10      tion has drafted “Guidelines for Hand Hygiene in  
11      Healthcare Settings” setting forth recommendations  
12      to promote improved hand hygiene practices and re-  
13      duce transmission of pathogenic microorganisms to  
14      patients and personnel in health care settings.

15           (6) According to the Centers for Disease Con-  
16      trol and Prevention, nosocomial infections affect ap-  
17      proximately 2 million patients annually in acute care  
18      facilities in the United States at an estimated direct  
19      patient care cost of approximately \$3.5 billion each  
20      year.

21           (7) The Congress encourages the continuation  
22      and acceleration of private sector efforts to take im-  
23      mediate steps to improve patient safety and recog-  
24      nizes the need for action in the public sector to com-  
25      plement these efforts.

1           (8) The research on patient safety unequivocally calls for a learning environment, where providers will feel safe to report health care errors, in order to improve patient safety.

5           (9) Voluntary data gathering systems are more supportive than mandatory systems in creating the learning environment referred to in paragraph (8) as stated in the Institute of Medicine's report.

9           (10) Promising patient safety reporting systems have been established throughout the United States, and the best ways to structure and use these systems are currently being determined, largely through projects funded by the Agency for Healthcare Research and Quality.

15          (11) Many organizations currently collecting patient safety information have expressed a need for protections that will allow them to review protected information so that they may collaborate in the development and implementation of patient safety improvement strategies. Currently, the State peer review protections provide inadequate conditions to allow the sharing of information to promote patient safety.

24          (12) In 2001, the Institute of Medicine released a report entitled "Crossing the Quality Chasm" that

1 found that the United States health care system  
2 does not consistently deliver high-quality care to pa-  
3 tients.

4 (b) PURPOSES.—The purposes of this Act are—

5 (1) to encourage a culture of safety and quality  
6 in the United States health care system by providing  
7 for a health care errors reporting system that both  
8 protects information and improves patient safety  
9 and quality of health care; and

10 (2) to ensure accountability by raising stand-  
11 ards and expectations for continuous quality im-  
12 provements in patient safety through the actions of  
13 the Secretary of Health and Human Services.

14 **SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

15 (a) IN GENERAL.—Title IX of the Public Health  
16 Service Act (42 U.S.C. 299 et seq.) is amended—

17 (1) in section 912(c), by inserting “, in accord-  
18 ance with part C,” after “The Director shall”;

19 (2) by redesignating part C as part D;

20 (3) by redesignating sections 921 through 928,  
21 as sections 931 through 938, respectively;

22 (4) in section 938(1) (as so redesignated), by  
23 striking “921” and inserting “931”; and

24 (5) by inserting after part B the following:

1       **“PART C—PATIENT SAFETY IMPROVEMENT**

2       **“SEC. 921. DEFINITIONS.**

3       “In this part:

4               “(1) IDENTIFIABLE INFORMATION.—The term  
5       ‘identifiable information’ means information that is  
6       presented in a form and manner that allows the  
7       identification of any provider, patient, or reporter of  
8       patient safety work product. With respect to pa-  
9       tients, such information includes any individually  
10      identifiable health information as that term is de-  
11      fined in the regulations promulgated pursuant to  
12      section 264(c) of the Health Insurance Portability  
13      and Accountability Act of 1996 (Public Law 104–  
14      191; 110 Stat. 2033).

15              “(2) NONIDENTIFIABLE INFORMATION.—The  
16      term ‘nonidentifiable information’ means informa-  
17      tion that is presented in a form and manner that  
18      prevents the identification of any provider, patient,  
19      or reporter of patient safety work product. With re-  
20      spect to patients, such information must be de-iden-  
21      tified consistent with the regulations promulgated  
22      pursuant to section 264(c) of the Health Insurance  
23      Portability and Accountability Act of 1996 (Public  
24      Law 104–191; 110 Stat. 2033).

25              “(3) PATIENT SAFETY EVALUATION SYSTEM.—  
26      The term ‘patient safety evaluation system’ means a

1 process that involves the collection, management, or  
2 analysis of information for submission to or by a pa-  
3 tient safety organization.

4 “(4) PATIENT SAFETY ORGANIZATION.—The  
5 term ‘patient safety organization’ means a private or  
6 public organization or component thereof that is cer-  
7 tified, through a process to be determined by the  
8 Secretary under section 925, to perform each of the  
9 following activities:

10 “(A) The conduct, as the organization or  
11 component’s primary activity, of efforts to im-  
12 prove patient safety and the quality of health  
13 care delivery.

14 “(B) The collection and analysis of patient  
15 safety work product that is submitted by pro-  
16 viders.

17 “(C) The development and dissemination  
18 of evidence-based information to providers with  
19 respect to improving patient safety, such as rec-  
20 ommendations, protocols, or information re-  
21 garding best practices.

22 “(D) The utilization of patient safety work  
23 product to carry out activities limited to those  
24 described under this paragraph and for the pur-  
25 poses of encouraging a culture of safety and of

1 providing direct feedback and assistance to pro-  
2 viders to effectively minimize patient risk.

3 “(E) The maintenance of confidentiality  
4 with respect to identifiable information.

5 “(F) The provision of appropriate security  
6 measures with respect to patient safety work  
7 product.

8 “(G) The submission of nonidentifiable in-  
9 formation to the Agency consistent with stand-  
10 ards established by the Secretary under section  
11 923(b) for any National Patient Safety Data-  
12 base.

13 “(5) PATIENT SAFETY WORK PRODUCT.—

14 “(A) The term ‘patient safety work prod-  
15 uct’ means any document or communication  
16 (including any information, report, record,  
17 memorandum, analysis, deliberative work, state-  
18 ment, or root cause analysis) that—

19 “(i) except as provided in subpara-  
20 graph (B), is developed by a provider for  
21 the purpose of reporting to a patient safety  
22 organization, and is reported to a patient  
23 safety organization;

24 “(ii) is created by a patient safety or-  
25 ganization; or



1 “(iii) would reveal the deliberations or  
2 analytic process of a patient safety evalua-  
3 tion system (as defined in paragraph (3)).

4 “(B)(i) Patient safety work product de-  
5 scribed in subparagraph (A)(i)—

6 “(I) does not include any separate in-  
7 formation described in clause (ii); and

8 “(II) shall not be construed to include  
9 such separate information merely by rea-  
10 son of inclusion of a copy of the document  
11 or communication involved in a submission  
12 to, or the fact of submission of such a copy  
13 to, a patient safety organization.

14 “(ii) Separate information described in this  
15 clause is a document or communication (includ-  
16 ing a patient’s medical record or any other pa-  
17 tient or hospital record) that is developed or  
18 maintained, or exists, separately from any pa-  
19 tient safety evaluation system.

20 “(C) Information available from sources  
21 other than a patient safety work product under  
22 this section may be discovered or admitted in a  
23 civil or administrative proceeding, if discover-  
24 able or admissible under applicable law.

25 “(6) PROVIDER.—The term ‘provider’ means—

1           “(A) an individual or entity licensed or  
2 otherwise authorized under State law to provide  
3 health care services, including—

4           “(i) a hospital, nursing facility, com-  
5 prehensive outpatient rehabilitation facil-  
6 ity, home health agency, and hospice pro-  
7 gram;

8           “(ii) a physician, physician assistant,  
9 nurse practitioner, clinical nurse specialist,  
10 certified nurse midwife, psychologist, cer-  
11 tified social worker, registered dietitian or  
12 nutrition professional, physical or occupa-  
13 tional therapist, or other individual health  
14 care practitioner;

15           “(iii) a pharmacist; and

16           “(iv) a renal dialysis facility, ambula-  
17 tory surgical center, pharmacy, physician  
18 or health care practitioner’s office, long-  
19 term care facility, behavioral health resi-  
20 dential treatment facility, clinical labora-  
21 tory, or community health center; or

22           “(B) any other person or entity specified  
23 in regulations by the Secretary after public no-  
24 tice and comment.

1 **“SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PROD-**  
2 **UCT.**

3 “(a) PRIVILEGE.—Notwithstanding any other provi-  
4 sion of law and subject to subsection (c), patient safety  
5 work product shall not be—

6 “(1) subject to a civil or administrative sub-  
7 poena or order;

8 “(2) subject to discovery in connection with a  
9 civil or administrative proceeding;

10 “(3) subject to disclosure pursuant to section  
11 552 of title 5, United States Code (commonly known  
12 as the Freedom of Information Act), or any other  
13 similar Federal or State law;

14 “(4) required to be admitted as evidence or oth-  
15 erwise disclosed in any State or Federal civil or ad-  
16 ministrative proceeding; or

17 “(5) if the patient safety work product is identi-  
18 fiable information and is received by a national ac-  
19 creditation organization in its capacity as a patient  
20 safety organization—

21 “(A) used by a national accreditation orga-  
22 nization in an accreditation action against the  
23 provider that reported the information;

24 “(B) shared by such organization with its  
25 survey team; or

1           “(C) required as a condition of accredita-  
2           tion by a national accreditation association.

3           “(b) REPORTER PROTECTION.—

4           “(1) IN GENERAL.—A provider may not use  
5           against an individual in an adverse employment ac-  
6           tion described in paragraph (2) the fact that the in-  
7           dividual in good faith reported information—

8           “(A) to the provider with the intention of  
9           having the information reported to a patient  
10          safety organization; or

11          “(B) directly to a patient safety organiza-  
12          tion.

13          “(2) ADVERSE EMPLOYMENT ACTION.—For  
14          purposes of this subsection, an ‘adverse employment  
15          action’ includes—

16          “(A) the failure to promote an individual  
17          or provide any other employment-related benefit  
18          for which the individual would otherwise be eli-  
19          gible;

20          “(B) an adverse evaluation or decision  
21          made in relation to accreditation, certification,  
22          credentialing, or licensing of the individual; and

23          “(C) a personnel action that is adverse to  
24          the individual concerned.

1           “(3) REMEDIES.—Any provider that violates  
2           this subsection shall be subject to a civil monetary  
3           penalty of not more than \$20,000 for each such vio-  
4           lation involved. Such penalty shall be imposed and  
5           collected in the same manner as civil money pen-  
6           alties under subsection (a) of section 1128A of the  
7           Social Security Act are imposed and collected.

8           “(c) DISCLOSURES.—Nothing in this section pro-  
9           hibits any of the following disclosures:

10           “(1) Voluntary disclosure of nonidentifiable in-  
11           formation.

12           “(2) Voluntary disclosure of identifiable infor-  
13           mation by a provider or patient safety organization,  
14           if such disclosure—

15           “(A) is authorized by the provider for the  
16           purposes of improving quality and safety;

17           “(B) is to an entity or person subject to  
18           the requirements of section 264(c) of the  
19           Health Insurance Portability and Accountability  
20           Act of 1996 (Public Law 104–191; 110 Stat.  
21           2033), or any regulation promulgated under  
22           such section; and

23           “(C) is not in conflict with such section or  
24           any regulation promulgated under such section.

1           “(3) Disclosure as required by law by a pro-  
2       vider to the Food and Drug Administration, or on  
3       a voluntary basis by a provider to a federally estab-  
4       lished patient safety program, with respect to an Ad-  
5       ministration-regulated product or activity for which  
6       that entity has responsibility, for the purposes of ac-  
7       tivities related to the quality, safety, or effectiveness  
8       of such Administration-regulated product or activity.

9           “(4) Disclosures of patient safety work product  
10      in accordance with this part by a provider to a pa-  
11      tient safety organization.

12      “(d) EFFECT OF TRANSFER, DISCLOSURE.—The fol-  
13      lowing shall not be treated as a waiver of any privilege  
14      or protection established under this part:

15           “(1) The transfer of any patient safety work  
16      product between a provider and a patient safety or-  
17      ganization.

18           “(2) Disclosure of patient safety work product  
19      as described in subsection (c).

20           “(3) The unauthorized disclosure of patient  
21      safety work product.

22      “(e) PENALTY.—

23           “(1) PROHIBITION.—Except as provided in this  
24      part, and subject to paragraphs (2) and (4), it shall  
25      be unlawful for any person to disclose patient safety

1 work product in violation of this section, if such dis-  
2 closure constitutes a negligent or knowing breach of  
3 confidentiality.

4 “(2) RELATION TO HIPAA.—The penalty  
5 under paragraph (3) for a disclosure in violation of  
6 paragraph (1) does not apply if the person would be  
7 subject to a penalty under section 264(c) of the  
8 Health Insurance Portability and Accountability Act  
9 of 1996 (Public Law 104–191; 110 Stat. 2033), or  
10 any regulation promulgated under such section, for  
11 the same disclosure.

12 “(3) AMOUNT.—Any person who violates para-  
13 graph (1) shall be subject to a civil monetary penalty  
14 of not more than \$10,000 for each such violation in-  
15 volved. Such penalty shall be imposed and collected  
16 in the same manner as civil money penalties under  
17 subsection (a) of section 1128A of the Social Secu-  
18 rity Act are imposed and collected.

19 “(4) SUBSEQUENT DISCLOSURE.—Paragraph  
20 (1) applies only to the first person that breaches  
21 confidentiality with respect to particular patient  
22 safety work product.

23 “(f) RELATION TO HIPAA.—

24 “(1) IN GENERAL.—For purposes of applying  
25 the regulations promulgated pursuant to section

1       264(c) of the Health Insurance Portability and Ac-  
2       countability Act of 1996 (Public Law 104–191; 110  
3       Stat. 2033)—

4               “(A) patient safety organizations shall be  
5       treated as business associates; and

6               “(B) activities of such organizations de-  
7       scribed in section 921(4) in relation to a pro-  
8       vider are deemed to be health care operations  
9       (as defined in such regulations) of the provider.

10              “(2) RULE OF CONSTRUCTION.—Nothing in  
11       this section shall be construed to alter or affect the  
12       implementation of such regulations or such section  
13       264(c).

14              “(g) NO LIMITATION OF OTHER PRIVILEGES.—  
15       Nothing in this section shall be construed to affect privi-  
16       leges, including peer review and confidentiality protec-  
17       tions, that are otherwise available under Federal or State  
18       laws.

19              “(h) NO LIMITATION ON CONTRACTS.—Nothing in  
20       this section shall be construed to limit the power of a pro-  
21       vider and a patient safety organization, or a patient safety  
22       organization and the Agency or any National Patient  
23       Safety Database, consistent with the provisions of this Act  
24       and other applicable law, to enter into a contract requiring



1 greater confidentiality or delegating authority to make an  
2 authorized disclosure.

3 “(i) RELATION TO STATE REPORTING REQUIRE-  
4 MENTS.—Nothing in this part shall be construed as pre-  
5 empting or otherwise affecting any State law requiring a  
6 provider to report information, including information de-  
7 scribed in section 921(5)(B), that is not patient safety  
8 work product.

9 “(j) CONTINUATION OF PRIVILEGE.—Patient safety  
10 work product of an organization that is certified as a pa-  
11 tient safety organization shall continue to be privileged  
12 and confidential, in accordance with this section, if the or-  
13 ganization’s certification is terminated or revoked or if the  
14 organization otherwise ceases to qualify as a patient safety  
15 organization.

16 “(k) REPORTS ON STRATEGIES TO IMPROVE PA-  
17 TIENT SAFETY.—

18 “(1) DRAFT REPORT.—Not later than the date  
19 that is 18 months after any National Patient Safety  
20 Database is operational, the Secretary, in consulta-  
21 tion with the Director, shall prepare a draft report  
22 on effective strategies for reducing medical errors  
23 and increasing patient safety. The draft report shall  
24 include any measure determined appropriate by the  
25 Secretary to encourage the appropriate use of such

1 strategies, including use in any federally funded pro-  
2 grams. The Secretary shall make the draft report  
3 available for public comment and submit the draft  
4 report to the Institute of Medicine for review.

5 “(2) FINAL REPORT.—Not later than 1 year  
6 after the date described in paragraph (1), the Sec-  
7 retary shall submit a final report to the Congress  
8 that includes, in an appendix, any findings by the  
9 Institute of Medicine concerning research on the  
10 strategies discussed in the draft report and any  
11 modifications made by the Secretary based on such  
12 findings.

13 **“SEC. 923. NATIONAL DATABASE.**

14 “(a) AUTHORITY.—

15 “(1) IN GENERAL.—In conducting activities  
16 under this part, the Secretary shall provide for the  
17 establishment and maintenance of a database to re-  
18 ceive relevant nonidentifiable patient safety work  
19 product, and may designate entities to collect rel-  
20 evant nonidentifiable patient safety work product  
21 that is voluntarily reported by patient safety organi-  
22 zations upon the request of the Secretary. Any data-  
23 base established or designated under this paragraph  
24 may be referred to as a ‘National Patient Safety  
25 Database’.

1           “(2) USE OF INFORMATION.—Information re-  
2       ported to any National Patient Safety Database  
3       shall be used to analyze national and regional statis-  
4       tics, including trends and patterns of health care er-  
5       rors. The information resulting from such analyses  
6       may be included in the annual quality reports pre-  
7       pared under section 913(b)(2).

8           “(3) ADVISORY ROLE.—The Secretary shall  
9       provide scientific support to patient safety organiza-  
10      tions, including the dissemination of methodologies  
11      and evidence-based information related to root  
12      causes and quality improvement.

13       “(b) STANDARDS.—In establishing or designating a  
14      database under subsection (a)(1), the Secretary shall, in  
15      consultation with representatives of patient safety organi-  
16      zations, the provider community, and the health informa-  
17      tion technology industry, determine common formats for  
18      the voluntary reporting of nonidentifiable patient safety  
19      work product, including necessary elements, common and  
20      consistent definitions, and a standardized computer inter-  
21      face for the processing of the work product. To the extent  
22      practicable, such standards shall be consistent with the  
23      administrative simplification provisions of part C of title  
24      XI of the Social Security Act.

1 “(c) CERTAIN METHODOLOGIES FOR COLLECTION.—

2 The Secretary shall ensure that the methodologies for the  
3 collection of nonidentifiable patient safety work product  
4 for any National Patient Safety Database include the  
5 methodologies developed or recommended by the Patient  
6 Safety Task Force of the Department of Health and  
7 Human Services.

8 “(d) FACILITATION OF INFORMATION EXCHANGE.—

9 To the extent practicable, the Secretary may facilitate the  
10 direct link of information between providers and patient  
11 safety organizations and between patient safety organiza-  
12 tions and any National Patient Safety Database.

13 “(e) RESTRICTION ON TRANSFER.—Only nonidentifi-

14 able information may be transferred to any National Pa-  
15 tient Safety Database.

16 **“SEC. 924. TECHNICAL ASSISTANCE.**

17 “(a) IN GENERAL.—The Secretary, acting through  
18 the Director, may—

19 “(1) provide technical assistance to patient  
20 safety organizations, and to States with reporting  
21 systems for health care errors; and

22 “(2) provide guidance on the type of data to be  
23 voluntarily submitted to any National Patient Safety  
24 Database.

1       “(b) ANNUAL MEETINGS.—Assistance provided  
2 under subsection (a) may include annual meetings for pa-  
3 tient safety organizations to discuss methodology, commu-  
4 nication, information collection, or privacy concerns.

5       **“SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZA-**  
6                               **TIONS.**

7       “(a) IN GENERAL.—Not later than 6 months after  
8 the date of enactment of the Patient Safety and Quality  
9 Improvement Act, the Secretary shall establish a process  
10 for certifying patient safety organizations.

11       “(b) PROCESS.—The process established under sub-  
12 section (a) shall include the following:

13               “(1) Certification of patient safety organiza-  
14 tions by the Secretary or by such other national or  
15 State governmental organizations as the Secretary  
16 determines appropriate.

17               “(2) If the Secretary allows other governmental  
18 organizations to certify patient safety organizations  
19 under paragraph (1), the Secretary shall establish a  
20 process for approving such organizations. Any such  
21 approved organization shall conduct certifications  
22 and reviews in accordance with this section.

23               “(3) A review of each certification under para-  
24 graph (1) (including a review of compliance with  
25 each criterion in this section and any related imple-

1       menting standards as determined by the Secretary  
2       through rulemaking) not less often than every 3  
3       years, as determined by the Secretary.

4               “(4) Revocation of any such certification by the  
5       Secretary or other such governmental organization  
6       that issued the certification, upon a showing of  
7       cause.

8       “(c) CRITERIA.—A patient safety organization must  
9       meet the following criteria as conditions of certification:

10              “(1) The mission of the patient safety organiza-  
11       tion is to conduct activities that are to improve pa-  
12       tient safety and the quality of health care delivery  
13       and is not in conflict of interest with the providers  
14       that contract with the patient safety organization.

15              “(2) The patient safety organization has appro-  
16       priately qualified staff, including licensed or certified  
17       medical professionals.

18              “(3) The patient safety organization, within any  
19       2 year period, contracts with more than 1 provider  
20       for the purpose of receiving and reviewing patient  
21       safety work product.

22              “(4) The patient safety organization is not a  
23       component of a health insurer or other entity that  
24       offers a group health plan or health insurance cov-  
25       erage.

1           “(5) The patient safety organization is man-  
2           aged, controlled, and operated independently from  
3           any provider that contracts with the patient safety  
4           organization for reporting patient safety work prod-  
5           uct.

6           “(6) To the extent practical and appropriate,  
7           the patient safety organization collects patient safety  
8           work product from providers in a standardized man-  
9           ner that permits valid comparisons of similar cases  
10          among similar providers.

11          “(d) ADDITIONAL CRITERIA FOR COMPONENT ORGA-  
12          NIZATIONS.—If a patient safety organization is a compo-  
13          nent of another organization, the patient safety organiza-  
14          tion must meet the following criteria as conditions of cer-  
15          tification:

16               “(1) The patient safety organization maintains  
17               patient safety work product separately from the rest  
18               of the organization, and establishes appropriate se-  
19               curity measures to maintain the confidentiality of  
20               the patient safety work product.

21               “(2) The patient safety organization does not  
22               make an unauthorized disclosure under this Act of  
23               patient safety work product to the rest of the orga-  
24               nization in breach of confidentiality.

1           “(3) The mission of the patient safety organiza-  
 2           tion does not create a conflict of interest with the  
 3           rest of the organization.”.

4           (b) AUTHORIZATION OF APPROPRIATIONS.—Section  
 5   937 of the Public Health Service Act (as redesignated by  
 6   subsection (a)) is amended by adding at the end the fol-  
 7   lowing:

8           “(e) PATIENT SAFETY AND QUALITY IMPROVE-  
 9   MENT.—For the purpose of carrying out part C, there are  
 10   authorized to be appropriated such sums as may be nec-  
 11   essary for each of the fiscal years 2003 through 2012.”.

12   **SEC. 4. PROMOTING THE DIFFUSION AND INTEROPER-**  
 13                   **ABILITY OF INFORMATION TECHNOLOGY SYS-**  
 14                   **TEMS INVOLVED WITH HEALTH CARE DELIV-**  
 15                   **ERY.**

16           (a) VOLUNTARY STANDARDS.—

17           (1) IN GENERAL.—Not later than 18 months  
 18           after the date of the enactment of this Act, the Sec-  
 19           retary of Health and Human Services (in this sec-  
 20           tion referred to as the “Secretary”) shall—

21                   (A) develop or adopt voluntary national  
 22                   standards that promote the interoperability of  
 23                   information technology systems involved with  
 24                   health care delivery, including but not limited to  
 25                   computerized physician order entry;



1 (B) in developing or adopting such stand-  
2 ards, take into account—

3 (i) the ability of such systems to cap-  
4 ture and aggregate clinically specific data  
5 to enable evidence-based medicine and  
6 other applications that promote the elec-  
7 tronic exchange of patient medical record  
8 information; and

9 (ii) the cost that meeting such stand-  
10 ards would have on providing health care  
11 in the United States and the increased effi-  
12 ciencies in providing such care achieved  
13 under the standards;

14 (C) in developing or adopting such stand-  
15 ards and to the extent practicable, test the effi-  
16 cacy, usability, and scalability of proposed inter-  
17 operability standards within a variety of clinical  
18 settings, including an urban academic medical  
19 center, a rural hospital, a community health  
20 center, and a community hospital; and

21 (D) submit a report to the Congress con-  
22 taining recommendations on such standards.

23 (2) CONSULTATION.—In developing or adopting  
24 standards under paragraph (1)(A), the Secretary  
25 shall consider the recommendations of the National

1 Committee on Vital Health Statistics for the stand-  
2 ardization of message formatting, coding, and vocab-  
3 ulary for interoperability of information technology  
4 systems involved with health care delivery. The Sec-  
5 retary shall consult with representatives of the  
6 health information technology industry and the pro-  
7 vider community who are involved with the develop-  
8 ment of interoperability standards.

9 (b) UPDATES.—The Secretary shall provide for the  
10 ongoing review and periodic updating of the standards de-  
11 veloped under subsection (a).

12 **SEC. 5. GRANTS FOR ELECTRONIC PRESCRIPTION PRO-**  
13 **GRAMS.**

14 (a) GRANTS.—

15 (1) IN GENERAL.—The Secretary of Health and  
16 Human Services (in this section referred to as the  
17 “Secretary”) may make grants to qualified practi-  
18 tioners for the purpose of establishing electronic pre-  
19 scription programs.

20 (2) MATCHING FUNDS.—

21 (A) IN GENERAL.—With respect to the  
22 costs of establishing an electronic prescription  
23 program, a condition for the receipt of a grant  
24 under paragraph (1) is that the qualified practi-  
25 tioner involved agree to make available (directly

1 or through donations from public or private en-  
2 tities) non-Federal contributions toward such  
3 costs in an amount that is not less than 50 per-  
4 cent of such costs.

5 (B) DETERMINATION OF AMOUNT CON-  
6 TRIBUTED.—Non-Federal contributions re-  
7 quired in subparagraph (A) may be in cash or  
8 in kind, fairly evaluated, including equipment or  
9 services. Amounts provided by the Federal Gov-  
10 ernment, or services assisted or subsidized to  
11 any significant extent by the Federal Govern-  
12 ment, may not be included in determining the  
13 amount of such non-Federal contributions.

14 (b) STUDY.—

15 (1) IN GENERAL.—The Secretary, acting  
16 through the Director of the Agency for Healthcare  
17 Research and Quality, shall support a study to as-  
18 sess existing scientific evidence regarding the effec-  
19 tiveness and cost-effectiveness of the use of elec-  
20 tronic prescription programs intended to improve the  
21 efficiency of prescription ordering and the safe and  
22 effective use of prescription drugs. The study shall  
23 address the following:

1           (A) The ability of such programs to reduce  
2           medical errors and improve the quality and  
3           safety of patient care.

4           (B) The impact of the use of such pro-  
5           grams on physicians, pharmacists, and patients,  
6           including such factors as direct and indirect  
7           costs, changes in productivity, and satisfaction.

8           (C) The effectiveness of strategies for over-  
9           coming barriers to the use of electronic pre-  
10          scription programs.

11          (2) REPORT.—The Secretary shall ensure that,  
12          not later than 18 months after the date of the enact-  
13          ment of this Act, a report containing the findings of  
14          the study under paragraph (1) is submitted to the  
15          appropriate committees of the Congress.

16          (3) DISSEMINATION OF FINDINGS.—The Sec-  
17          retary shall disseminate the findings of the study  
18          under paragraph (1) to appropriate public and pri-  
19          vate entities.

20          (c) DEVELOPMENT OF MODEL.—The Secretary, act-  
21          ing through the Director of the Agency for Healthcare Re-  
22          search and Quality, may develop an Internet-based mathe-  
23          matical model that simulates the cost and effectiveness of  
24          electronic prescription programs for qualified practi-  
25          tioners. The model may be designed to allow qualified

1 practitioners to estimate, through an interactive interface,  
 2 the impact of electronic prescribing on their practices, in-  
 3 cluding the reduction in drug-related health care errors.

4 (d) DEFINITIONS.—For purposes of this section:

5 (1) The term “electronic prescription pro-  
 6 gram”—

7 (A) means a program for the electronic  
 8 submission of prescriptions to pharmacies or  
 9 pharmacy benefit managers and the processing  
 10 of such submissions by pharmacies; and

11 (B) includes the hardware (including com-  
 12 puters and other electronic devices) and soft-  
 13 ware programs for the electronic submission of  
 14 prescriptions to pharmacies, the processing of  
 15 such submissions by pharmacies, and decision-  
 16 support programs.

17 (2) The term “qualified practitioner” means a  
 18 practitioner licensed by law to administer prescrip-  
 19 tion drugs.

20 **SEC. 6. GRANTS TO HOSPITALS AND OTHER HEALTH CARE**  
 21 **PROVIDERS FOR INFORMATION TECH-**  
 22 **NOLOGIES.**

23 (a) IN GENERAL.—The Secretary of Health and  
 24 Human Services (in this section referred to as the “Sec-  
 25 retary”) shall make grants to hospitals and other health

1 care providers (but not more than 1 grant to any 1 hos-  
2 pital or provider) to pay the costs of acquiring or imple-  
3 menting information technologies whose purposes are—

4 (1) to improve quality of care and patient safe-  
5 ty; and

6 (2) to reduce adverse events and health care  
7 complications resulting from medication errors.

8 (b) SPECIAL CONSIDERATION.—In making grants  
9 under subsection (a), the Secretary shall give special con-  
10 sideration to applicants who seek to promote the following:

11 (1) Interoperability across hospital services or  
12 departments using standards developed or adopted  
13 by the Secretary under section 4.

14 (2) Electronic communication of patient data  
15 across the spectrum of health care delivery.

16 (3) Computerized physician order entry or bar  
17 coding applications.

18 (4) Electronic communication of patient data in  
19 hospitals that provide services to underserved or low-  
20 income populations.

21 (5) Improved clinical decisionmaking through  
22 acquisition and implementation of decision-support  
23 technologies.

1       (c) CERTAIN GRANT CONDITIONS.—A condition for  
2 the receipt of a grant under subsection (a) is that the ap-  
3 plicant involved meet the following requirements:

4           (1) The applicant agrees to carry out a pro-  
5 gram to measure, analyze, and report patient safety  
6 and medical errors at the hospital or other health  
7 care provider involved, to submit to the Secretary a  
8 description of the methodology that will be used, and  
9 to have such program in effect as soon as prac-  
10 ticable after the application for the grant is ap-  
11 proved, without regard to whether information tech-  
12 nologies under the grant have been implemented.

13          (2) The applicant has arranged for an evalua-  
14 tion that addresses the effectiveness and cost-effec-  
15 tiveness of the information technology for which the  
16 grant is provided and its impact on the quality and  
17 safety of patient care, submitted the evaluation plan  
18 to the Secretary, and received approval from the  
19 Secretary of the applicant's methodology.

20          (3) The applicant has or is developing a patient  
21 safety evaluation system (as that term is defined in  
22 section 921 of the Public Health Service Act (as  
23 amended by section 3)) for reporting health care er-  
24 rors to a patient safety organization.

1           (4) The applicant agrees to provide the Sec-  
2       retary with such information as the Secretary may  
3       require regarding the use of funds under this pro-  
4       gram or its impact.

5           (5) The applicant provides assurances satisfac-  
6       tory to the Secretary that any information tech-  
7       nology planned, acquired, or implemented with grant  
8       funds under this section will be part of an informa-  
9       tion program that—

10           (A) carries out the purposes described in  
11       subsection (a); and

12           (B) is comprehensive or will be expanded  
13       to become comprehensive, regardless of whether  
14       Federal assistance is available for such expan-  
15       sion.

16       (d) TECHNICAL ASSISTANCE TO GRANTEES.—The  
17       Secretary, acting through the Director of the Agency for  
18       Healthcare Research and Quality, shall provide technical  
19       assistance to applicants and grantees to ensure the appro-  
20       priate evaluation of the information technologies for which  
21       grants are awarded under this section, such as—

22           (1) reviewing and providing technical assistance  
23       on the applicant’s proposed evaluation;

24           (2) developing mechanisms to ensure ongoing  
25       communications between grantees and evaluators to



1 facilitate the identification and resolution of prob-  
2 lems as they arise, ensure mutual learning, and pro-  
3 mote the rapid dissemination of information;

4 (3) reviewing the interim and final reports re-  
5 quired under subsection (e); and

6 (4) disseminating evidence-based information in  
7 interim and final reports to patient safety organiza-  
8 tions, as appropriate.

9 (e) EVALUATION REPORTS BY GRANTEE.—A condi-  
10 tion for the receipt of a grant under subsection (a) is that  
11 the applicant agree to submit an interim and a final report  
12 to the Secretary in accordance with this subsection.

13 (1) INTERIM REPORT.—Not later than 1 year  
14 after the implementation of information technologies  
15 under the grant is completed, the applicant will sub-  
16 mit an interim report to the Secretary describing the  
17 initial effectiveness of such technologies in carrying  
18 out the purposes described in subsection (a).

19 (2) FINAL REPORT.—Not later than 3 years  
20 after the implementation of information technologies  
21 under the grant is completed, the applicant will sub-  
22 mit a final report to the Secretary describing the ef-  
23 fectiveness and cost-effectiveness of such tech-  
24 nologies and addressing other issues determined to

1 be important in carrying out the purposes described  
2 in subsection (a).

3 (3) RELATION TO DISBURSEMENT OF GRANT.—

4 In disbursing a grant under subsection (a), the Sec-  
5 retary shall withhold  $\frac{1}{3}$  of the grant until the grant-  
6 ee submits to the Secretary the report required in  
7 paragraph (1).

8 (f) REPORTS BY SECRETARY.—

9 (1) INTERIM REPORTS.—

10 (A) IN GENERAL.—Through the fiscal year  
11 preceding the fiscal year in which the final re-  
12 port under paragraph (2) is prepared, the Sec-  
13 retary shall submit to the Committee on Energy  
14 and Commerce of the House of Representatives  
15 and the Committee on Health, Education,  
16 Labor, and Pensions of the Senate periodic re-  
17 ports on the grant program under subsection  
18 (a). Such reports shall be submitted not less  
19 frequently than once each fiscal year, beginning  
20 with fiscal year 2004.

21 (B) CONTENTS.—A report under subpara-  
22 graph (A) shall include information on—

23 (i) the number of grants made;

1 (ii) the nature of the projects for  
2 which funding is provided under the grant  
3 program;

4 (iii) the geographic distribution of  
5 grant recipients; and

6 (iv) such other matters as the Sec-  
7 retary determines appropriate.

8 (2) FINAL REPORT.—Not later than 180 days  
9 after the date on which the last of the reports is due  
10 under subsection (e)(2), the Secretary shall submit  
11 a final report to the committees referred to in para-  
12 graph (1)(A) on the grant program under subsection  
13 (a), together with such recommendations for legisla-  
14 tion and administrative action as the Secretary de-  
15 termines appropriate.

16 (g) DEFINITIONS.—For purposes of this section:

17 (1) The term “costs”, with respect to informa-  
18 tion technologies referred to in subsection (a), in-  
19 cludes total expenditures incurred for—

20 (A) purchasing, leasing, and installing  
21 computer software and hardware, including  
22 hand-held computer technologies;

23 (B) making improvements to existing com-  
24 puter software and hardware; and

1 (C) purchasing or leasing communications  
2 capabilities necessary for clinical data access,  
3 storage, and exchange.

4 (2) The term “health care provider” has the  
5 same meaning given to the term “provider” in sec-  
6 tion 921 of the Public Health Services Act (as  
7 amended by this Act).

8 (h) TERMINATION OF GRANT AUTHORITIES.—The  
9 authority of the Secretary to make grants under sub-  
10 section (a) terminates upon the expiration of fiscal year  
11 2011.

12 (i) MATCHING FUNDS.—

13 (1) IN GENERAL.—With respect to the costs of  
14 a grant to be carried out under this section, such  
15 grant may be made only if the applicant agrees to  
16 make available (directly or through donations from  
17 public or private entities) non-Federal contributions  
18 toward such costs in an amount that is not less than  
19 50 percent of such costs (\$1 for each \$1 of Federal  
20 funds provided in the grant).

21 (2) DETERMINATION OF AMOUNTS CONTRIB-  
22 UTED.—Amounts provided by the Federal Govern-  
23 ment, or services assisted or subsidized to any sig-  
24 nificant extent by the Federal Government, may not

1 be included in determining the amount of such non-  
 2 Federal contributions.

3 (j) AUTHORIZATION OF APPROPRIATIONS.—

4 (1) IN GENERAL.—For the purpose of carrying  
 5 out this section, there are authorized to be appro-  
 6 priated such sums as may be necessary for each of  
 7 the fiscal years 2003 through 2011.

8 (2) AVAILABILITY.—Amounts appropriated  
 9 under paragraph (1) remain available for obligation  
 10 through fiscal year 2011.

11 **SEC. 7. REQUIRED USE OF PRODUCT IDENTIFICATION**  
 12 **TECHNOLOGY.**

13 The Federal Food, Drug, and Cosmetic Act (21  
 14 U.S.C. 301 et seq.) is amended—

15 (1) in section 502, by adding at the end the fol-  
 16 lowing:

17 “(u) If it is a drug or biological product, unless it  
 18 includes a unique product identifier for the drug or bio-  
 19 logical product as required by regulations under section  
 20 510(o).”; and

21 (2) in section 510, by adding at the end the fol-  
 22 lowing:

23 “(o)(1) The Secretary shall issue, and may periodi-  
 24 cally revise, regulations requiring the manufacturer of any  
 25 drug or biological product that is subject to regulation by

1 the Food and Drug Administration, or the packager or  
2 labeler of a drug or biological product that is subject to  
3 regulation by the Food and Drug Administration, to in-  
4 clude a unique product identifier on the packaging of the  
5 drug or biological product.

6 “(2) For purposes of this subsection, the term  
7 ‘unique product identifier’ means an identification that—

8 “(A) is affixed by the manufacturer, labeler, or  
9 packager to each drug or biological product de-  
10 scribed in paragraph (1) at each packaging level;

11 “(B) uniquely identifies the item and meets the  
12 standards required by this section; and

13 “(C) can be read by a scanning device or other  
14 technology acceptable to the Secretary.

15 “(3) A unique product identifier required by regula-  
16 tions issued or revised under paragraph (1) shall be based  
17 on—

18 “(A) the National Drug Code maintained by  
19 the Food and Drug Administration;

20 “(B) commercially accepted standards estab-  
21 lished by organizations that are accredited by the  
22 American National Standards Institute, such as the  
23 Health Industry Business Communication Council or  
24 the Uniform Code Council; or

1           “(C) other identification formats that the Sec-  
2       retary deems appropriate.

3       “(4) The Secretary may, at the Secretary’s discre-  
4       tion, waive the requirements of this section, or add addi-  
5       tional provisions that are necessary to safeguard the pub-  
6       lic health.”.

○